

Serial No. 10/058,891

B8
25. (Amended): A gelatin capsule containing enteric fluoxetine pellets sufficient to administer 60-120 mg base equivalent of fluoxetine, wherein the pellets comprise a core consisting of fluoxetine and one or more pharmaceutically acceptable excipients and an enteric layer comprising hydroxypropylmethylcellulose acetate succinate (HPMCAS) and one or more pharmaceutically acceptable excipients.

According to 37 CFR 1.121(c)(1)(ii), amendments to Claims 19 and 25 are shown on separate sheets marked up to show the changes and attached to this reply as Attachment 1.

As permitted under 37 CFR 1.121(c)(3) Applicants attach a clean version of the entire set of pending claims as Attachment 2.

Remarks

Claims 19 and 25 have been amended in response to issues raised by the Examiner. Entry of the amendments and reconsideration of the claims in view of the amendments and discussion infra are respectfully requested.

Rejections Under 35 U.S.C. § 112

Claims 19 and 25 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter that Applicants regard as their invention. The Examiner objects to the placement of the term "sufficient" in claims 19 and 25 as originally presented, allegedly because the claims as originally presented include elements not actually disclosed, thereby rendering the scope of the claims unascertainable. Applicants have amended the claims as suggested by the Examiner, thereby obviating the Examiner's rejection. Entry of the amendments and withdrawal of the rejection in view of the amendments are respectfully requested.

Defective Oath or Declaration

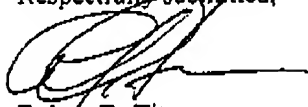
The Examiner has required Applicants to file a new oath or declaration because the original declaration allegedly failed to point out a specific error being corrected. A new declaration accompanies this response, specifically stating the error being corrected by the present reissue application. Entry of the new declaration is respectfully requested.

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The Examiner has also found the originally presented declaration deficient because the present reissue application is allegedly a broadening reissue, and therefore must be signed by the inventors rather than the assignee. The Examiner has characterized the present reissue application as broadening in view of the increase in the upper limit of the dosage range recited in claims 19 and 25 of the present reissue application relative to claims 19, 31, and 38 of U.S. Patent #5,910,319. Applicants respectfully submit that the Examiner has incorrectly characterized the scope of the present reissue application as broadening relative to that of U.S. Patent #5,910,319.

The present reissue application is not a broadening reissue because the recited range of 60-120 mg base equivalent of fluoxetine is narrower than the broadest scope claimed in U.S. Patent #5,910,319. "[A] claim which has been *broadened in a reissue as compared to its scope in the patent* is not a broadened reissue claim if it is narrower than, or equal in scope to, any other claim which appears in the patent." (M.P.E.P. § 1412.03, emphasis in original). Claim 1 of U.S. Patent #5,910,319 contains no dosage range limitation. Claims 19, 31, and 38 of U.S. Patent #5,910,319 depend either directly or indirectly from Claim 1, and add the dosage range limitation of 20-100 mg base equivalent of fluoxetine. Claims 19 and 25 of the present reissue application have been presented in independent form and recite a dosage range of 60-120 mg base equivalent of fluoxetine, a range that Applicants respectfully submit is narrower than the scope of Claim 1 of U.S. Patent #5,910,319. As such, present claims 19 and 25 are not broadened reissue claims. Reconsideration and withdrawal of the characterization of the present reissue application as a broadening reissue and the requirement of a new oath or declaration signed by the inventors are respectfully requested.

Respectfully submitted,



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Eli Lilly and Company
Patent Division
P.O. Box 6288
Indianapolis, Indiana 46206-6288

July 29, 2003

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ATTACHMENT 1

19. (Amended): A formulation of [sufficient] enteric fluoxetine pellets sufficient to administer 60-120 mg base equivalent of fluoxetine, wherein the pellets comprise a core consisting of fluoxetine and one or more pharmaceutically acceptable excipients and an enteric layer comprising hydroxypropyl-methylcellulose acetate succinate (HPMCAS) and one or more pharmaceutically acceptable excipients.

25. (Amended): A gelatin capsule containing [sufficient] enteric fluoxetine pellets sufficient to administer 60-120 mg base equivalent of fluoxetine, wherein the pellets comprise a core consisting of fluoxetine and one or more pharmaceutically acceptable excipients and an enteric layer comprising hydroxypropylmethylcellulose acetate succinate (HPMCAS) and one or more pharmaceutically acceptable excipients.

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ATTACHMENT 2

19. A formulation of enteric fluoxetine pellets sufficient to administer 60-120 mg base equivalent of fluoxetine, wherein the pellets comprise a core consisting of fluoxetine and one or more pharmaceutically acceptable excipients and an enteric layer comprising hydroxypropylmethylcellulose acetate succinate (HPMCAS) and one or more pharmaceutically acceptable excipients.

20. A formulation of Claim 1 administering about 80-90 mg base equivalent of fluoxetine.

21. A formulation of Claim 1 administering about 90 mg of base equivalent of fluoxetine.

22. A formulation of Claim 19 wherein the fluoxetine is present as fluoxetine hydrochloride.

23. A formulation of Claim 20 wherein the fluoxetine is present as fluoxetine hydrochloride.

24. A formulation of Claim 21 wherein the fluoxetine is present as fluoxetine hydrochloride.

25. A gelatin capsule containing enteric fluoxetine pellets sufficient to administer a dose of 60-120 mg base equivalents of fluoxetine, wherein the pellets comprise a core consisting of fluoxetine and one or more pharmaceutically acceptable excipients and an enteric layer comprising hydroxypropylmethylcellulose acetate succinate (HPMCAS) and one or more pharmaceutically acceptable excipients.

26. A gelatin capsule of Claim 25, wherein about 80-90 base equivalents of fluoxetine are administered.

27. A formulation of Claim 19 containing the following:

Cores

Sucrose - starch nonpareils, 30-35 mesh	100-150
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mg

Fluoxetine layer

Fluoxetine hydrochloride	100.5-100.8 mg
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Sucrose	20-30 mg
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Hydroxypropylmethylcellulose	10-15 mg
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Separating layer

Hydroxypropylmethylcellulose	4-12 mg
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Sucrose	15-35 mg
Talc, 500 mesh	25-60 mg
Enteric layer	
HPMCAS-LF	60-90 mg
Triethyl citrate	10-20 mg
Talc, 500 mesh	15-25 mg
Finishing layer	
Color mixture white (HPMC + titanium dioxide)	35-55 mg
HPMC	5-15 mg
Talc	Trace.

28. A gelatin capsule of Claim 25, wherein about 90 mg base equivalent of fluoxetine are administered.

29. A formulation according to Claim 19 wherein the formulation additionally contains pindolol.

30. A method of treating a patient suffering from depression, obsessive-compulsive disorder, bulimia, pain, obsessive-compulsive personality disorder, post-traumatic stress disorder, hypertension, atherosclerosis, anxiety, anorexia nervosa, panic, social phobia, stuttering, sleep disorders, chronic fatigue, Alzheimer's disease, alcohol abuse, appetite disorders, weight loss, agoraphobia, improving memory, amnesia, smoking cessation, nicotine withdrawal syndrome symptoms, disturbances of mood and/or appetite associated with pre-menstrual syndrome, depressed mood and/or carbohydrate craving associated with pre-menstrual syndrome, disturbances of mood, disturbances of appetite or disturbances which contribute to recidivism associated with nicotine withdrawal, circadian rhythm disorder, borderline personality disorder, hypochondriasis, pre-menstrual syndrome (PMS), late luteal phase dysphoric disorder, pre-menstrual dysphoric disorder, trichotillomania, symptoms following discontinuation of other antidepressants, aggressive/intermittent explosive disorder, compulsive gambling, compulsive spending, compulsive sex, psychoactive substance use disorder, sexual disorder, schizophrenia, premature ejaculation, or psychiatric symptoms selected from stress, worry, anger, rejection sensitivity, and lack of mental or physical energy comprising administering a formulation of Claim 19.

31. A method of Claim 30 employing a formulation administering about 80-90 mg base equivalent of fluoxetine.

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32. A method of Claim 30 employing a formulation administering about 90 mg base equivalent of fluoxetine.

33. A method of Claim 30 wherein the fluoxetine is present as fluoxetine hydrochloride.

34. A method of Claim 31 wherein the fluoxetine is present as fluoxetine hydrochloride.

35. A method of Claim 32 wherein the fluoxetine is present as fluoxetine hydrochloride.

36. A method of Claim 30 employing a formulation containing the following:

Cores

Sucrose - starch nonpareils, 30-35 mesh	100-150 mg
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Fluoxetine layer

Fluoxetine hydrochloride	100.5-100.8 mg
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Sucrose	20-30 mg
---------	----------

Hydroxypropylmethylcellulose	10-15 mg
------------------------------	----------

Separating layer

Hydroxypropylmethylcellulose	4-12 mg
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Sucrose	15-35 mg
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Talc, 500 mesh	25-60 mg
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Enteric layer

HPMCAS-LF	60-90 mg
-----------	----------

Triethyl citrate	10-20 mg
------------------	----------

Talc, 500 mesh	15-25 mg
----------------	----------

Finishing layer

Color mixture white (HPMC + titanium dioxide)	35-55 mg
---	----------

HPMC	5-15 mg
------	---------

Talc	Trace.
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37. A method of Claim 30 of treating a patient suffering from pain, further comprising the coadministration of morphine, codeine or dextropropoxyphene.

38. A method of Claim 37 employing a formulation administering about 80-90 mg base equivalent of fluoxetine.

39. A method of Claim 37 employing a formulation administering about 90 mg base equivalent of fluoxetine.

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40. A formulation of Claim 19, wherein the pellets further comprise a separating layer.
41. A formulation of Claim 40, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.
42. A formulation of Claim 19, wherein the pellets further comprise a finishing layer.
43. A formulation of Claim 40, wherein the pellets further comprise a finishing layer.
44. A formulation of Claim 41, wherein the pellets further comprise a finishing layer.
45. A formulation of Claim 21, wherein the pellets further comprise a separating layer.
46. A formulation of Claim 45, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.
47. A formulation of Claim 21, wherein the pellets further comprise a finishing layer.
48. A formulation of Claim 45, wherein the pellets further comprise a finishing layer.
49. A formulation of Claim 46, wherein the pellets further comprise a finishing layer.
50. A gelatin capsule of Claim 25, wherein the pellets further comprise a separating layer.
51. A gelatin capsule of Claim 50, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.
52. A gelatin capsule of Claim 25, wherein the pellets further comprise a finishing layer.
53. A gelatin capsule of Claim 50, wherein the pellets further comprise a finishing layer.
54. A gelatin capsule of Claim 51, wherein the pellets further comprise a finishing layer.
55. A gelatin capsule of Claim 28, wherein the pellets further comprise a separating layer.
56. A gelatin capsule of Claim 55, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

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- (57) A gelatin capsule of Claim 28, wherein the pellets further comprise a finishing layer.
- (58) A gelatin capsule of Claim 55, wherein the pellets further comprise finishing layer.
- (59) A gelatin capsule of Claim 56, wherein the pellets further comprise a finishing layer.
60. A method of Claim 30, wherein the pellets further comprise a separating layer.
61. A method of Claim 60, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.
62. A method of Claim 30, wherein the pellets further comprise a finishing layer.
63. A method of Claim 60, wherein the pellets further comprise a finishing layer.
64. A method of Claim 61, wherein the pellets further comprise a finishing layer.
65. A method of Claim 32, wherein the pellets further comprise a separating layer.
66. A method of Claim 65, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.
67. A method of Claim 32, wherein the pellets further comprise a finishing layer.
68. A method of Claim 65, wherein the pellets further comprise a finishing layer.
69. A method of Claim 66, wherein the pellets further comprise a finishing layer.
70. A method of Claim 30 without an increase in nausea.
71. A method of Claim 32 without an increase in nausea.
72. A method of Claim 36 without an increase in nausea.
73. A method of Claim 37 without an increase in nausea.
74. A method of Claim 38 without an increase in nausea.
75. A method of Claim 39 without an increase in nausea.

#26
10-22/03

Docket No.: X-10709B
Application No.: 10/058,891
Filing Date: January 28, 2002

**REISSUE DECLARATION BY THE ASSIGNEE, POWER OF
ATTORNEY, AND SURRENDER OF PATENT**

I hereby declare that:

My residence, post office address and citizenship
are as stated below next to my name.

I am authorized to act on behalf of the following
assignee: Eli Lilly and Company, and the title of my position
with said assignee is General Patent Counsel.

The entire title to the patent identified below is
vested in said assignee.

I believe Neil R. Anderson, Roger G. Harrison,
Daniel F. Lynch, and Peter L. Oren are the original, first and
joint inventors of the subject matter which is claimed and for
which United States Patent No. 5,910,319 was granted on June
8, 1999 for the invention entitled

**FLUOXETINE ENTERIC PELLETS AND METHODS FOR THEIR PREPARATION
AND USE**

the specification of which:

☒ is attached hereto
☐ was filed on _____
as United States Application Serial No. _____

or

PCT International Application No. _____
and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand
the contents of the above-identified specification, including
the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information that
is material to patentability as defined in 37 C.F.R. 1.56.

I believe the original patent to be wholly or partly
inoperative or invalid, by reason of the patentee claiming
more than he had a right to claim in the patent.

At least one error upon which reissue is based is
described as follows:

The lower limit of the dosage range in Claims 19, 31
and 38 is too low, encompassing doses of less than 60 mg base
equivalent of fluoxetine.

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Page 2

I state that the above-identified errors arose without any deceptive intention on the part of the applicants.

I surrender the above-identified letters patent which accompanies this paper and request that the letters patent be reissued to the said Eli Lilly and Company for the same invention upon the foregoing specification.

Power of Attorney: I hereby appoint the following attorneys and/or agents to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

<u>Attorney</u>	<u>Reg. No.</u>	<u>Attorney</u>	<u>Reg. No.</u>
Arvie J. Anderson	45,263	Gerald P. Kelerher	43,707
Lynn D. Apelgren	45,341	James J. Kolley	41,888
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Michael T. Bates	34,121	Kirby Lee	47,744
Roger S. Benjamin	27,025	Robert E. Lee	27,919
Gary M. Birch	48,881	James P. Leeds	35,241
William R. Boudreaux	35,796	Nelsen L. Lentz	38,537
Steven P. Caltrider	36,467	Douglas K. Norman	33,267
Paul R. Cantrell	36,470	Arleen Palmberg	40,422
John Cleveland	P50,697	Thomas G. Plant	35,784
Charles E. Cohen	34,565	Edward Prein	37,212
Donald L. Corneglio	30,741	Grant E. Reed	41,264
Gregory A. Cox	47,504	James J. Sales	33,773
Paula K. Davis	47,517	Michael J. Sayles	32,295
Elizabeth A. Dawalt	44,646	Robert L. Sharp	45,609
John C. Demeter	30,167	David M. Stemerick	40,187
Manisha A. Desai	43,585	Mark J. Stewart	43,936
Joanna Longo Feehey	35,134	Robert D. Titus	40,206
Paul J. Gaylo	36,808	Robert C. Tucker	45,165
Francis O. Ginah	44,712	Tina M. Tucker	47,145
Janet A. Gongola	48,436	MaCharri Vorndran-Jones	36,711
Amy E. Hamilton	33,894	Gilbert T. Voy	43,972
James A. Hoffmann	P50,221	Thomas D. Webster	39,872
Frederick D. Hunter	26,915	Lawrence T. Welch	29,487
Thomas E. Jackson	33,064	Alexander Wilson	45,782
Soonhee Jang	44,802	Dan L. Wood	48,613
Charles Joyner	30,466		

said Robert A. Armitage and Douglas K. Norman to have in addition the power to revoke the power granted to all others listed above.

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Direct Telephone Calls To:

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317-277-3729

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I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Full Name of Person

Signing : Douglas K. Norman

Signature :

Douglas K. Norman

Date: 29 July 2003

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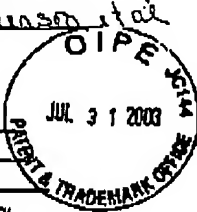
Docket No. X-10709B
Page 4

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Joint Inventor : Peter Lloyd Oren

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Fishers, Indiana 46038

Post Office Address : SAME AS ABOVE

Citizenship : United States

PATENT		Dkt. No. <u>X-107098</u> Atty. <u>RDT</u>	
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Serial No. <u>10/058891</u>	OR	Interference No. _____	
Filed: <u>1-28-2002</u>		Parties: _____	
Applicants: <u>Amgen, Inc.</u>			
Response _____		Amendment/Response <input checked="" type="checkbox"/>	
IDS/1449 _____		Assignment/Cover Sheet _____	
Notice of Appeal _____		Issue Fee _____	
Letter Trans./Brief _____		Express Abandonment _____	
Affirm 821/Diskette _____		Fee Authorization _____	
Trans./Decl. Power Atty _____		Communication _____	
Other Papers: <u>Reissu Declaration</u>			
Certificate of Mailing /			

Fax

Lilly

Eli Lilly and Company
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To: EXAMINER C. L. EVANS

Company: USPTO
Fax: 703-746-5035
Date: OCTOBER 1, 2003

From: ROBERT TITUS
Fax: 317-277-1917
Total Pages: 15

If you have any questions concerning the content of this message, please call:
ROBERT TITUS 317-277-3729

EXAMINER EVANS:

THIS FAX INCLUDES OUR RESPONSE MAILED JULY 29, 2003, AS
WELL AS THE RETURN POSTCARD INDICATING RECEIPT BY THE
RECEIVING OFFICE ON JULY 31, 2003.

THANK-YOU - 

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Answers That Matter